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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,409	06/30/2003	Steven M: Fischer	10010632-3	1968

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,409

Applicant(s)

FISCHER, STEVEN M.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

The applicant's response filed 8/30/06 to the Office action has been entered. Claims 21-34, and 42-43 are pending.

1. The rejection of claims 21-34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,613,523 is withdrawn because of the terminal disclaimer filed.
2. The rejection of claims 21-34 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment and the argument.
3. Claims 21-31, 33-34 and 42-43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (WO 99/02728, issued January 21, 1999).

Schmidt et al. disclose that a series of DNA fragments is provided by contacting a template in the presence of DNA polymerase with a mixture of nucleotides sufficient for hybridizing to the template for forming a second strand of DNA complementary to the template. The mixture comprises a set of four probes containing all four nucleotides for hybridizing to the template in which the nucleotide of each probe comprises a modified nucleotide, which is capable of polymerizing to the second strand of DNA, but blocked to prevent further polymerization and which is cleavably attached to the mass label. The mass label is identified by mass spectrometry for the modified nucleotide (See pg. 3, paragraph 5 and pg. 4, paragraph 1). The mass label is corresponding to a modified nucleotide so that the nucleotide present in the target template may be deduced (See pg. Paragraph 4). The cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). Ligating is also used to produce extended products (See pg. 12, paragraph 1 and 3). The cleavable tag is a

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3' cleavable tag (See pg. 46, paragraph 5, fig. 4a and fig. 13) in which the cleavable tag is attached to the 3' end.

Schmidt et al. do not explicitly disclose the cleavable tag is an acid or base cleavable tag as recited in claims 29 and 30. However, Schmidt et al. disclose that the cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). This teaching is inherent that the cleavable tag is an acid or base cleavable tag. Thus, the teachings of Schmidt et al. anticipate the limitations of Schmidt et al.

The response argues that Schmidt et al. do not disclose cleaving a 3' cleavable tag from the extension product to produce a cleaved tag and an extension product that includes at least one complementary nucleotide that is hybridized to the nucleic acid sequence. However, based upon the recited paragraph from the prior art, the teachings in the paragraph do not necessarily mean that the extension product is to be dissociated and separated from the nucleic acid template prior to cleaving the cleavable tag from the nucleic acid. Actually, the teachings of Schmidt et al. satisfy the limitation "cleaving a 3' cleavable tag from the extension product to produce a cleaved tag and an extension product that includes at least one complementary nucleotide that is hybridized to the nucleic acid sequence" because Schmidt et al. disclose that the nucleic acid fragments which are extended product and are separated (See the Abstract, fig. 4, 13, and 14). Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al. (WO 99/02728, issued January 21, 1999) as applied to claims 21-31, and 33-34 in view of Cheeseman et al. (5,302,509, issued Apr. 12, 1994).

The teachings of Schmidt et al. are set forth in section 3 above. Schmidt et al do not disclose that the cleavable tag is a fluorescent tag.

Cheeseman et al. disclose a method for determining the sequence of nucleotides on a single strand DNA in which the cleavable tag is a fluorescent tag (See column 2, lines 57-59 and column 6, lines 11-13).

One of ordinary skill in the art would have been motivated to apply a fluorescent tag for the cleavable tag because Cheeseman et al. apply ^{ce}the fluorescent for the cleavable tag for nucleic acid sequencing. It would have been prima facie obvious to apply a fluorescent tag for the cleavable tag for nucleic acid sequencing.

NEW GROUND REJECTION IS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation “to produce a hybridization product composition” has no support in the specification based on the page and lines recited in the specification.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 22-24 and 43 ^{are} ~~is~~ rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 43 is vague and indefinite because of the phrase “a hybridization product composition”. It is unclear what is the definition of the phrase in the specification.
- b. Claims 22-24 are vague and indefinite because of the phrase “a single cleavable tag terminated deoxynucleotide triphosphate”. It is unclear what is encompassed by the phrase. Clarification is required.

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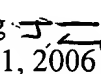
Summary


10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung 
November 1, 2006


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

11/2/06

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